

## **REMARKS**

Upon entry of the amendment, claims 1, 8-10, 12-13, 33-45, 105-107, and 111-112 are pending. Claims 1, 8, 13, 39-42, and 105-107 have been amended and claims 2-4, 7, 14, 24-32, 101-104, and 110 have been cancelled. Support for the amendment made in claim 1 can be found at least at page 1, line 2 of the as-filed specification. Support for new claims 111 and 112 can be found at page 51, lines 19-28. No new matter has been added.

### **Information Disclosure Statement**

The Examiner has requested that Applicants submit the Information Disclosure Statement that was submitted on February 26, 2006 but was unavailable, however, Applicants do not believe that an Information Disclosure Statement was filed on that date and therefore Applicants have not submitted a copy.

### **Claim Objections**

The Examiner objected to claim 7. Claim 7 has been cancelled. As such, the objection is moot and Applicants request that the objection be withdrawn.

### **Rejection under 35 USC § 112, first paragraph**

Claims 1-4, 7-10, 12-14, 24-26, 33-45, 101-107, and 110 are rejected under 35 USC § 112, first paragraph for lack of enablement. The Examiner states that although the specification is enabling for the species gastrin and GLP-1. Claims 1 and 13, from which the remainder of claims depend, have been amended accordingly. Applicants request that the rejection be withdrawn.

### **Rejection under 35 USC § 102**

Claims 13-14 and 24 are rejected as being anticipated by Ramiya (US 2002/0182728). The Examiner also states that Sheridan (US 2003/0032183) teaches a method for inducing pancreatic islet neogenesis in a mammal. The application requires administration to a mammal and the rejection is to Ramiya and Sheridan which are both directed to culturing stem cells in

vitro and do not teach or suggest administering to a mammal a gastrin and a GLP-1. As such, Applicants request the rejection be withdrawn.

### **Rejection under 35 USC § 103**

Claims 1-3, 7-10, 12-14 and 24-25 are rejected as obvious over Parikh et al (US 6,558,952) in view of Hoffman (US 6,358,924). Claims 1 and 13, from which the remaining claims depend, have been amended to recite a composition comprising a gastrin and GLP-1.

It is well recognized under U.S. law, that any rejection of a claim for obviousness over a combination of prior art references must establish that: (1) the combination produces the claimed invention; and (2) the prior art contains a suggestion or motivation to combine the prior art references in such a way as to achieve the claimed invention.<sup>1</sup> The motivation to modify the prior art must flow from some teaching in the art that suggests the desirability or incentive to make the modification needed to arrive at the claimed invention.<sup>2</sup> The mere fact that the prior art could be modified does not make the modification obvious unless the prior art suggests the desirability of the modification.<sup>3</sup>

Contrary to the Examiner's assertions, the combination provided unexpected results that would not have been obvious to a person skilled in the art. Parikh teaches a method of treating diabetes using gastrin/CCK receptor ligand, which encompass a number of compounds that stimulate the gastrin/CCK receptor, including gastrin 34, gastrin 17, gastrin 8, CCK 58, CCK 33, CCK 22, CCK 12 and CCK 8. (Parikh, column 6, lines 9-18). Parikh further suggests using gastrin/CCK in combination with EGF receptor ligands which include EGF1-53, and fragments and analogs thereof. (Parikh, column 6, lines 26-34). Parikh does not suggest using gastrin in combination with GLP-1, in fact, Parikh teaches away from GLP-1 to the extent it suggests gastrin/CCK in combination with EGF receptor ligands.

Hoffman does not teach or suggest administering gastrin. (Hoffman, column 1, lines 20-37). Hoffman teaches using a formulation of GLP-1 and a surfactant, it does not teach using GLP-1 in combination with another receptor ligand such as gastrin. Parikh does not suggest using gastrin and GLP-1 to treat diabetes. Additionally, Hoffman does not teach using GLP-1

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<sup>1</sup> In re Vaeck, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

<sup>2</sup> In re Napier, 34 U.S.P.Q.2d 1782, 1784 (Fed. Cir. 1995).

<sup>3</sup> In re Laskowski, 10 U.S.P.Q.2d 1397, 1399 (Fed. Cir. 1989).

and gastrin but rather teaches a formulation of GLP-1 containing surfactants. There is no motivation to combine the Parikh and Hoffman.

The Examiner asserts that Parikh teaches a method of treating diabetes by administering to the individual in need thereof a composition including gastrin, but does not teach administering GLP-1 and Hoffman teaches a method of treating diabetes by administering a composition including GLP-1. The Examiner further states that it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the gastrin and GLP-1 for their known benefit since each is well known in the art for the treatment of diabetes and that the present invention is predicated on an unexpected result, which typically involves synergism, an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular ingredients.

Although the Examiner stated that no unexpected results were observed, Example 1 of the specification shows that treatment with GLP-1 and gastrin was more effective at reducing fasting blood glucose levels than either gastrin alone or GLP-1 alone. Treatment with the combination reduced fasting blood glucose levels to a level in the normal range. This result is unexpected and due to gastrin and GLP-1 working in combination to treat diabetes rather than singularly or with another compound as in Parikh or Hoffman.

The Examiner has also rejected claims 1, 33-35, 39-45 and 104 as being obvious over Parikh et al, in view of Hoffman and in view of Baeder et al (EP 0507555 A1), which teaches a method for treating diabetes by administering rapamycin. (Baeder, page 1, lines 1-2). As stated above, prior art needs to suggest or motivate a combination of references in order to make an invention obvious. Baeder teaches a method of treating diabetes using rapamycin, however, the reference does not teach or suggest using rapamycin in combination with gastrin and/or GLP-1. Instead, Baeder teaches using rapamycin in combination with insulin to treat diabetes. As such, there is no motivation to combine Parikh and Hoffman and Baeder, and as such the rejection should be withdrawn.

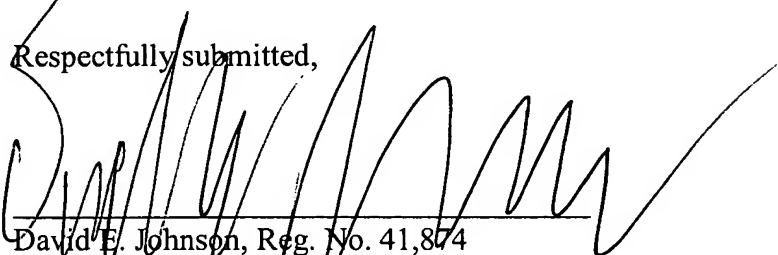
### **Double Patenting**

Claims 1-4, 7-10, 12-14, and 14-16 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 13, 21, 32, 91-92 and 101 of copending Application No. 10/532,295. Applicants will address any

double-patenting issues with respect to the claims pending in the present application and the claims in the '295 application upon the indication of allowable subject matter in the '295 application.

The Commissioner is authorized to charge any additional fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0311, Reference No. 24492-011.

Respectfully submitted,



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